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**UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/367,748 11/19/99 DIEMBECK

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EXAMINER
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LAMM, M	
ART UNIT	PAPER NUMBER

1616  
DATE MAILED:

8  
10/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
**09/367,748**

Applicant(s)  
**Diembeck et al.**

Examiner  
**Marina Lamm**

Group Art Unit  
**1616**



- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-17 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-17 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1616

### DETAILED ACTION

Claims 1-17 are pending in this application filed 11/19/99 under 35 U.S.C 371 based on PCT/EP98/00991 filed 02/20/98 and German applications 197 06 581.3 and 197 11 565.9 filed 02/21/97 and 03/20/97, respectively.

#### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 2, 4-8 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of rosacea and couperose, does not reasonably provide enablement for the prophylaxis of these conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The enabling disclosure is limited to the treatment of rosacea and couperose as indicated above. The burden of enabling the prophylaxis or prevention of a disease (i.e. the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to prevent the condition. Further, the specification does not provide guidance as to

Art Unit: 1616

how one skilled in the art would go about screening those patients susceptible to rosacea and couperose. Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compounds in preventing these disease states. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

Applicant's claims must be commensurate in scope with the enabling disclosure. Applicant is advised that the claim can not be broader than the supporting disclosure.

3. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for NO-synthase inhibitors disclosed on pp.2-5 of the instant specification, does not reasonably provide enablement for any other NO-synthase inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enabling disclosure is limited to the specific compounds as indicated above.

Applicant's claims must be commensurate in scope with the enabling disclosure. Applicant is advised that the claim can not be broader than the supporting disclosure.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 and those dependent thereon are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1616

Claim 1 recited the phrase "an effective amount". This phrase is indefinite because the claim fails to state the function to be achieved by the recited compounds. See MPEP 2173.05 (c), III.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-16 are rejected under 35 U.S.C. 102(e) as being anticipated by either Breton et al. (US 5,795,574) or Ptchelintsev et al. (US 5,847,003).

Breton et al. teach cosmetic or pharmaceutical preparations containing anti-inflammatory substances including NO-synthase inhibitors such as N<sup>G</sup>-monomethyl-L-arginine, N<sup>G</sup>-nitro-L-arginine, N<sup>G</sup>-nitro-L-arginine methyl ester, etc. See col. 9, lines 12-21; col. 11, lines 31-56. The preparations of Breton et al. may also contain antioxidants and sunscreens agents. See col. 16, lines 52 and 53.

Ptchelintsev et al. teach cosmetic compositions containing NO-synthase inhibitors, including N<sup>G</sup>-nitro-L-arginine and N<sup>G</sup>-monomethyl-L-arginine, which are effective in reducing skin redness,

Art Unit: 1616

vasodilation and inflammatory reactions. See col. 9, lines 40-53. The compositions of Ptchelintsev et al. may also contain antioxidants and organic and inorganic sunscreens. See col. 6, lines 51-67; col. 9, line 61.

The compositions of Breton et al. and Ptchelintsev et al. will inherently treat rosacea and couperose when applied to the skin. Under the doctrine of “inherency”, prior art may anticipate a claim if it “inherently” possesses all of the elements of the claimed invention, even if it “did not fully appreciate the uses, purposes, or properties of the product or process’ created. General Electric Company v. Hoechst Celanese Corp., 740 F. Supp. 305, 312 (D. Del. 1990).

Thus, Breton et al. and Ptchelintsev et al. teach each and every limitation of Claims 1-16.

8. Claims 1-3, 7-10 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahluwalia et al. (WO 95/24884).

Ahluwalia et al. teach cosmetic compositions containing NO synthase inhibitors in dermatologically acceptable vehicle. See p. 3, lines 14-19. The NO synthase inhibitors include N<sup>G</sup>-methyl-L-arginine, N<sup>G</sup>-nitro-L-arginine and its esters, N-acetyl-L-arginine, N-benzoyl-L-arginine, etc.

The compositions of Ahluwalia et al. will inherently treat rosacea and couperose when applied to the skin. Under the doctrine of “inherency”, prior art may anticipate a claim if it “inherently” possesses all of the elements of the claimed invention, even if it “did not fully appreciate the uses, purposes, or properties of the product or process’ created. General Electric Company v. Hoechst Celanese Corp., 740 F. Supp. 305, 312 (D. Del. 1990).

Thus Ahluwalia et al. teach each and every limitation of Claims 1-3, 7-10 and 14-17.

Art Unit: 1616

9. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Bloy et al. (US 5,478,821).

Bloy et al. teach NO synthase inhibitors having acylated amino group. See Abstract.

Thus, Bloy et al. teach each and every limitation of Claim 17 as claimed.

10. Claims 1-4, 7-11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Giacomoni (WO 96/26711).

Giacomoni teaches cosmetic compositions containing at least one NO synthase inhibitor in cosmetically acceptable carrier. See Abstract. The compositions of Giacomoni may be used for the treatment of various skin conditions, including rosacea. See p. 8, line 41. The NO synthase inhibitors of Giacomoni include N<sup>G</sup>-monomethyl-L-arginine, N<sup>G</sup>-nitro-L-arginine and its methyl ester, N<sup>G</sup>,N<sup>G</sup>-dimethyl-L-arginine and N<sup>G</sup>-amino-L-arginine. See p. 4, lines 29-35. Antioxidants such as vitamins E and A may be used in the composition. See p. 7, lines 36-37.

Thus, Giacomoni teaches each and every limitation of Claims 1-4, 7-11 and 14-16.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

12. Claims 5, 6, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giacomoni in view of either Breton et al. or Ptchelintsev et al.

Giacomoni applied as above.

Giacomoni does not teach sunscreens agents of Claims 5, 6, 12 and 13.

However, it is conventional to employ sunscreens agents in cosmetic compositions. See Breton et al. at col. 16, line 53 or Ptchelintsev et al. at col. 6, lines 54-67.

One of ordinary skill would have been motivated to employ sunscreens agents of Breton et al. or Ptchelintsev et al. in compositions of Giacomoni with a reasonable expectation of beneficial results such as sun protecting effect.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

13. No claims are allowed at this time.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,723,451 and US 5,837,738 - disclose NO synthase inhibitors suitable to topical application.

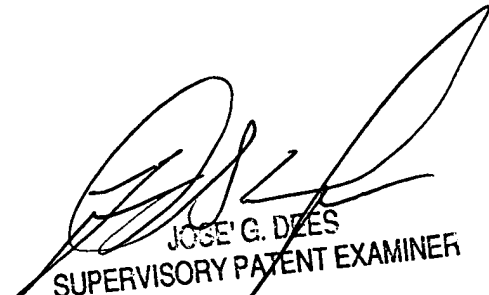
Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ml  
October 6, 2000

  
JOSE G. DZES  
SUPERVISORY PATENT EXAMINER  
1616